

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: Clark et al.	Group Art Unit: 3771
Application No: 09/414,384 Confirmation No: 3236	Examiner: Dixon, Annette Fredricka
Filed: October 7, 1999	Attorney Docket No: 53235-US-CNT (NV.0037.00)
Title: FLOW RESISTANCE MODULATED AEROSOLIZED ACTIVE AGENT DELIVERY	March 29, 2010 San Francisco, California

**REPLY BRIEF**

VIA ELECTRONIC FILING

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Examiner:

In response to the Examiner's Answer mailed on January 29, 2010, the Applicant of the above-referenced patent application (hereinafter Appellant) hereby maintains the appeal to the Board of Patent Appeals and Interferences. Appellant requests the reversal of the Final Rejection.

**Certificate of Transmission**

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By:

  
Melanie Hitchcock

Date: March 29, 2010

***Status of Claims***

Claims 21-36 are presently pending in the case. Claims 21-36 have been finally rejected. The rejection of each of claims 21-36 is hereby appealed.

Claims 1-20 have been cancelled.

***Grounds of Rejection to be Reviewed on Appeal***

Appellant continues to request review of the Examiner's following grounds of rejection:

Claims 21, 24, 28, 32, 34 and 36 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent 5,479,920 to Piper et al (hereinafter Piper et al).

Claims 22, 23, 26, 27, 30, 31 and 33 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Piper et al.

Claims 25, 29 and 35 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Piper et al in view of U.S. Patent 4,227,522 to Carris (hereinafter Carris).

## **Argument**

Appellant believes claims 21-36 are improperly rejected and are therefore allowable for the reasons set forth in Appellant's Appeal Brief filed on October 28, 2009. The present Reply Brief is being filed to specifically address some of the issues raised by the Examiner in the Examiner's Answer mailed on January 29, 2010. The comments herein are merely supplemental to the arguments made in the Appeal Brief and are not meant to replace those arguments.

### The rejections continue to be improper

Appellant has invented a novel aerosolization device that comprises a valve that initially has a high flow resistance and that subsequently opens to provide a lower flow resistance. By this arrangement, a user has difficulty inhaling through the device at the onset of inhalation. The prior art discloses valves that have the opposite arrangement (*i.e.*, low flow resistance initially followed by higher flow resistance). Thus, the present arrangement is unconventional and counter-intuitive.

The Examiner has applied Piper et al against the claims. Though Piper et al does not disclose a device and valve that are similar to that invented by Appellant, the Examiner appears to be of the position that Appellant's claims are sufficiently broad to "read on" a device as unrelated to Appellant's invention as Piper et al is. To make the rejection, the Examiner stretches the teachings of Piper et al in several directions. Appellant disagrees with each of the contortions for the reasons set forth in Appellant's Appeal Brief.

Notwithstanding the fact that the Examiner's interpretations of Piper et al vis-à-vis the claims is unfair and not within the construct of 35 U.S.C. §102(b), the Examiner never accounts for the limitation in claim 21 that the initial flow resistance is at least  $0.4 \text{ (cm H}_2\text{O)}^{1/2}$  / SLM in the inhalation direction. Piper et al's valve is a one-way valve that allows flow in the inhalation direction and offers little, if any, resistance to inhalation

flow. The Examiner states that “during exhalation, the valve (24) is closed and has a resistance of infinity.” (Page 10, line 21 of Examiner’s Answer). The Examiner offers no evidentiary (or even logical) support for this contention. Furthermore, the contention is without relevance because Appellant’s claim is concerned only with inhalation resistance. The Examiner goes on to speculate about backside pressure build-up. However, as discussed in the Appeal Brief, any such pressure build-up would: (i) not relate to the valve’s structural flow resistance, and (ii) not come close to amounting to the extremely high flow resistance of at least  $0.4 \text{ (cm H}_2\text{O)}^{1/2} / \text{SLM}$ .

More fundamentally, the Examiner has confused the terms “flow” and “flow resistance”. Appellant has defined a structural feature of a device in terms of its flow resistance, as discussed in the Appeal Brief. Whatever the pressure situation in Piper et al, it has no relevance to the system’s flow resistance.

## Conclusion

Thus, it is believed that all rejections made by the Examiner have been addressed and overcome by the above arguments and the arguments provided in the Appeal Brief. Therefore, all pending claims are allowable. A reversal is respectfully requested.

Should there be any questions, Appellant's representative may be reached at the number listed below.

Respectfully submitted,

JANAH & ASSOCIATES

Dated: March 29, 2010

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